

**REMARKS**

This is in full and timely response to the above-identified Office Action. The above listing of the claims supersedes any previous listing. Favorable reexamination and reconsideration are respectfully requested in view of the preceding amendments and the following remarks.

**Claim amendments/Status**

Claims 1, 12, 13, 14, 15 and 19 have been amended. New claims 21, 22 have been added.

**Claim rejections – 35 USC § 112**

Claim 19 has been amended to recite only one range. New claims 21 and 22 have been added to recite each of the deleted ranges in amended claim 19.

No other rejections were raised regarding claim 19, and thus it is respectfully submitted that claims 19, 21 and 22 are allowable for at least that reason.

**Claim rejections – 35 USC § 102**

The rejection of claims 1 and 12 under 35 USC § 102(b) as being anticipated by US 6,450,170, is respectfully traversed.

Claim 1 has been amended to read:

*1. A method for treatment of hard tissue present in a fluid-filled body cavity, wherein the fluid-filled body cavity is selected from salivary ducts and temporomandibular joints, the cavity having a diameter of 3 mm or less, the method comprising:*

*(a) generating a laser beam by an Er:YAG laser device, said laser beam having a wavelength of about 2940nm; and*

*(b) applying said laser beam to said hard tissue, or to a proximity of said hard tissue.*

Thus, this claim recites the manipulative step (a) of "generating a laser beam", in which the laser beam has "a wavelength of about 2940nm", as produced by an Er:YAG laser device.

In contrast, US 6,450,170 does not disclose or in any way suggest generating such a laser beam, nor applying such a laser beam to hard tissue, in contrast to the present invention. Rather, US 6,450,170 discloses using a Helium Neon laser, which emits a laser of wavelength 632.8nm, and this is done for the purpose of relieving pain, and not the treatment of hard tissue

*per se* that may be present in a fluid filled cavity (column 4, lines 45-63), in contrast to claim 1.

Claim 12 as presently amended relates to:

*12. An endoscopic device comprising an aperture adapted for connecting to a Er:YAG laser having an optic fiber for insertion into a body cavity having a diameter of 3mm or less.*

US 6,450,170 does not disclose or in any way suggest such an endoscopic device, and column 4, lines 58-60 cited by the Examiner merely states:

*"He-Ne low level radiation has been used in treatment of temporomandibular joint pain, trigeminal neuralgia, facial and muscular pain, etc."*

It is therefore respectfully submitted that claims 1 and 12 are both novel and inventive over the disclosure of US 6,450,170 when taken as a whole.

Claim rejections – 35 USC § 103

The rejection of claims 1, 3-18, 20 under 35 USC § 103(a) as being unpatentable over the ADKit publication in view of the Teichman et al. publication, is respectfully traversed.

The Examiner states on page 5 that *"a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference"*.

Applicant respectfully submits that each specialty in the field of medicine requires many years for a man to acquire **ordinary skill** in the particular specialty or art. Thus what may be obvious or "common sense" in **Otolaryngology** for a man of ordinary skill in **Otolaryngology** may not be obvious at all to a man of ordinary skill in the art of **Urology**. In each case, the man of ordinary skill in the art is in fact a specialist in the particular art, and the threshold for what constitutes "ordinary" is relatively high, requiring particular and extensive training, experience and knowledge in the art. Typically a man of ordinary skill in one such art does not also have "ordinary skill" in another art, even though they may both be medical arts, and thus, each one of the ADKIT and Teichman publication is directed to an entirely different man of ordinary skill in an entirely different "art".

In any case, while the ADKIT publication is a specialized **Otolaryngology** publication, and relates to an **in-vivo** endoscopic laser lithotripsy of a proximal parotid duct calculus, it only suggests **limited success** in using holmium:YAG laser. Specifically, this reference states that

one successful endoscopic laser lithotripsy was conducted in 1994 by a Spanish group (page 1, 3<sup>rd</sup> paragraph), and a second such procedure no less than 6 years later (i.e., reported in 2001 in the reference) by a different team. Thus, a man of the art in the field of **Otolaryngology** understands that endoscopic laser lithotripsy of the parotid duct is a rare Otolaryngological procedure, which has special problems associated with the small, tight nature of the body cavity.

As mentioned before, the Teichman et al publication is a specialized Urology publication, and is thus not expected to be within the purview of a man of ordinary skill in the field of Otolaryngology, and relates, in contrast to the ADKIT reference, to *in-vivo* comparative testing of an Erbium:YAG laser and a Holmium:YAG laser, in the context of urinary tract calculi.

The Teichman reference specifically attributes the efficiency of the Erbium:YAG laser "as a result of the inherent absorption characteristics of *urinary* calculi at erbium wavelengths and the efficient delivery through *water*" (page 878, right column, 1<sup>st</sup> paragraph). Moreover, it states clearly that the "Er:YAG laser used in the study was a laboratory grade laser in which the design was not optimized for clinical applications" (page 878, left column, 3<sup>rd</sup> paragraph).

Therefore, it is respectfully submitted that there is no clear "common sense" argument that would compel a man of the art in **Otolaryngology** to combine the two references, but rather the opposite:

- the two references relate to completely different medical specialized disciplines relating to anatomically different parts of the body;
- in one reference Holmium:YG laser treatment is disclosed as being extremely rare in that medical field, while in the other reference Holmium:YG laser treatment is quite common in the other medical field;
- one reference relates to in-vivo, while the other relates to in-vitro with no direction as to optimality for clinical applications;
- the composition of urinary calculi is different from that of salivary calculi. Optimal wavelengths for laser ablation may depend on the chemical composition of the calculi (page 877, left column, 5<sup>th</sup> paragraph) and specifically attributes the efficiency of the Erbium:YAG laser "as a result of the

inherent absorption characteristics of *urinary* calculi at erbium wavelengths" (page 878, right column, 1<sup>st</sup> paragraph). Thus, there is no "common sense" indication whatsoever that comparative results obtained with respect to urinary calculi have to read over to salivary calculi.

- the ADKIT reference teaches away from expensive clinical procedures (page 1, 1<sup>st</sup> paragraph), while in contrast the Teichman references discloses that fibers that were used in the in-vitro tests were relatively expensive (page 2, right column, 1<sup>st</sup> paragraph).

Furthermore, the Teichman reference admits that the "fragmentation efficiency" of the Er:YAG laser as compared with the Ho:YAG laser, i.e., "defined as laser fluence may not be **clinically relevant**" (page 878, left column, 2<sup>nd</sup> paragraph), and thus teaches away from replacing a Ho:YAG laser with a Er:YAG laser when used in-vivo.

In addition, it is to be noted that in the Taichman reference, carrying out tests in-vitro where the calculi were placed in "beakers full of water" (page 1, right column, second paragraph), while providing a possible comparable environment for the calculi in the context of large cavities associated with urinary calculi, **are far removed from the in-vivo environment of salivary duct calculi**, and thus "common sense" would dictate to a man of the art of *Otolaryngology* that such a test is meaningless in the context of in vivo *Otolaryngology*.

In fact, the Teichman et al publication fully **teaches away** from using Erbium lasers for **small body cavities**, particularly when considered with the teachings of the ADKIT publication. As clearly stated in the Teichman et al publication, page 876, left column, 1<sup>st</sup> paragraph, Holmium:YAG lasers work by means of a **photothermal mechanism**, in which the stone compositions are heated by the laser till they fragment. In the second paragraph, it is stated that optical energy is more efficiently absorbed by urinary calculi at the wavelength associated with an Erbium:YAG laser. In page 2, right column, 4<sup>th</sup> paragraph, this reference clearly states that "as optical energy is absorbed the stone surface temperature is increased". **This, taken with the previous paragraph above, implies that use of an Erbium:YAG laser in the restricted volume of a small body cavity such as the salivary duct, for example, would be expected to result in rapid heating thereof to a temperature much higher than would be achieved by a Ho:YAG laser.** This further suggests to a man of ordinary skill in the art of *Otolaryngology* that using such a laser in the context of a very small body cavity may cause

substantial damage to the tissue, and thus this reference teaches away from using an Erbium:YAG laser for small body cavities such as salivary ducts and temporomandibular joints.

It is respectfully submitted that the use of Erbium (Er:YAG) lasers for treatment of small fluid filled cavities such as *salivary ducts and temporomandibular joints* is not an obvious extension of the use of such lasers in other medical fields. The significant heating effects produced by such lasers in applications to large body cavities, such as kidneys for example, are of no concern, as the bulk of tissue and liquids can absorb part of the heat. On the other hand, such potential heating effects as would be expected by a man of the art to occur in small body cavities would be detrimental to the patient, as in contrast there is no bulk tissue or fluids to absorb the additional heat generated, and thus would be considered to cause damage to the small body cavity tissues.

Thus, it is respectfully submitted that the combination of references cannot reasonably be expected to teach a man of ordinary skill in the art to replace a Holmium laser with a Er:YAG laser for the treatment of small body cavities, when "common sense" in the art of ***Otolaryngology*** clearly suggests that overheating a small body cavity is harmful, and wherein "common sense" further suggests that an Er:YAG laser produces more heat than a Holmium laser which cannot easily be dissipated in such small cavities in the same relatively harmless way that such heat is dissipated in large body tissues such as kidneys. Thus, even if a Er:YAG laser may be considered to be more "efficient" than Holmium lasers, "common sense" to a man of ordinary skill in the art dictates that the safety of the patient is far more important than laser efficiency.

It is to be noted that the present application states that it is a surprising finding (page 5, line 26 to page 6, line 7) that Er:YAG lasers can actually be successfully used for small body cavities.

**Conclusion**

It is thus respectfully submitted that the present invention, as claimed in claims 1, 3-18 and 20 are novel and inventive over the cited references. Favorable reconsideration and allowance of this application are courteously solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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